

### REMARKS

Reconsideration of this application is respectfully requested. The specification has been amended to correct a typographical error which is discussed below. Claim 1 has been amended to incorporate the groups which can convert to a cyano group or a dimethylamino group into the definitions of R and Z, respectively. The definitions of R and Z do not include hydroxyl, amino, or MgHal groups. Furthermore, the definition of R<sup>1</sup> has been amended to exclude these groups. Claims 41 and 42 have been added. Support for these amendments is found in the specification at, for example, page 21, line 17 to page 22, line 2, and page 23, lines 12-33. Accordingly, no new matter has been added. Claims 1-42 are pending and at issue.

Claims 1, 10, 11, 13, 15-21, and 23-27 have been rejected as lacking enablement of (a) the entire scope of cyclic anhydrides and imides recited in claim 1, (b) all the recited substituents at R, R<sup>1</sup>, Y, and Z, (c) all techniques for separating compounds of formula (IV) from esters of formula (V), and (d) the conversions of R, Hal, and Z groups in any order.

According to the Examiner, the isolation and purification steps in claim 1 depend on the respective solubilities of the compound of formula (IV) and the compound of formula (V) generated from the recited anhydrides and imides. The Examiner asserts that the specification provides no information regarding the solubilities of compounds other than those formed from succinic anhydride or the suitability of solvents other than tetrahydrofuran to precipitate compounds of formula (V). The Examiner concludes that only cyclic anhydrides of formulas (Ia) and (Ib) where n=0, Q<sup>1</sup> and Q<sup>2</sup> are both carbon, and R', R'', and R''' are hydrogen or alkyl are enabled.

The reaction in step (a) of claim 1 involves the nucleophilic addition of the primary hydroxyl group of the diol of formula (II) to one of the acyl groups of the cyclic anhydrides and imides, which cleaves the bond between the carbonyl and the adjacent oxygen (or nitrogen in the case of the imides). *See* specification, page 2, lines 14-16; page 4, line 5 to page 5, line 6. Each of the recited cyclic anhydrides and imides possesses the functional groups that in the above reaction result in the acylation of the diol of formula (II). Therefore, a skilled artisan would generally expect the scope of recited anhydrides and imides to be operative.

Moreover, it is not necessary to provide detailed information about the solubilities of each compound of formula (V) formed from a specific anhydride or imide or about the solvents that are suitable to precipitate them. The specification must merely enable the skilled artisan to make and use the claimed invention without undue experimentation. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). The claims do not require the isolation of the compound of formula (IV) in a particular yield or to a certain degree of purity. Thus, the speculation by the Examiner that certain compounds of formula (V) may be more difficult to separate is largely irrelevant. The skilled artisan would, with routine effort, be able to react the recited anhydrides and imides with the mixture of compounds of formulas (II) and (IV) and separate at least some of the resulting compound of formula (V).

Furthermore, the specification need not disclose everything necessary to practice the invention in order to satisfy the enablement requirement. "In fact, what is well-known is best omitted." MPEP § 2164.08 (citing *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991)). The skilled artisan would be able to determine suitable solvents for the reaction based on the guidance provided by specification. *See* specification at page 13, lines 20-25. Also, it is not actually necessary that the compound of formula (V) forms a precipitate in the particular solvent. The specification teaches that in solvents where no precipitate forms an anti-solvent may be added to cause the compound of formula (V) to precipitate. *See* specification at page 13, lines 27-29.

The Examiner also asserts that some R, R<sup>1</sup>, Y, and Z substituents would defeat the claimed isolation and purification method. The Examiner states that R<sup>1</sup> groups such as alkylthio and hydroxyl; R groups such as OH, CH<sub>2</sub>OH, and CH<sub>2</sub>NH<sub>2</sub>; and Z groups such as MgHal are reactive like the hydroxyl group of the diol of formula (II).

Without conceding the validity of the Examiner's position, claim 1 has been amended to delete hydroxyl, amino, and MgHal from among the substituents at R and R<sup>1</sup> and to specify the groups that may be converted to cyano or dimethylaminomethyl. The applicants submit that the Examiner's concerns have been addressed. Moreover, as discussed above, the claims do not specify that the desired reaction must be the favored reaction. It is possible that side reactions may occur

that limit the formation of the compound of formula (V) and decrease the purity of the compound of formula (IV) in the reaction product.

Also, according to the Examiner, the specification provides no insight into the interaction of the R and Z moieties of compounds of formula (IV) with a basic resin or their effects on differential solubilities in a biphasic extraction system. Therefore, the Examiner concludes that the specification only enables separation by precipitation of a crystalline compound of formula (V).

Liquid-liquid extraction and ion exchange are well-known separation techniques. The skilled artisan would readily be able to determine appropriate solvents, conditions, and resins for separating the compounds of formulas (IV) and (V). Again, the specification does not have to provide detailed information about the parameters that give the greatest purity for every cyclic anhydride, every substituent, and every solvent. The applicants respectfully submit that the specification provides sufficient detail and insight to allow the skilled artisan to successfully perform the purification step.

Finally, the Examiner contends that claims 10 and 11 are not enabled for the conversion of R, Hal, and Z groups “in any order”. According to the Examiner, these groups may be reactive as discussed above, and the specification provides that the functional group conversions are preferentially carried out after ring closure to form a compound of formula (V).

The applicants first note that the specification at page 23, lines 5 and 8 contain an inadvertent error. The ring closure referred to is performed to convert the compounds of formulas (IV) and (V) to the compound of formula (VI), not formula (V). *See* specification at page 14, lines 8-19. The specification has been amended to correct this error.

As discussed above, the isolation and purification method of claim 1 is enabled for the substituents at R, Hal, and Z. Claims 10 and 11 relate to the conversion of the isolated compounds of formulas (V) and (IV), respectively, to a compound of formula (VI), where the substituents at R, Hal, and Z may be optionally converted to cyano, fluoro, and dimethylaminomethyl, respectively,

either before or after the conversion of compounds (IV)/(V) to compound (VI). The claims specify that the conversions may be performed “in any order”, i.e., where more than one substituent is converted, they may be converted in any order. For example, if both R and Hal are converted, it does not matter if R is converted first or if Hal is converted first. The Examiner has provided no rationale for why these conversions (either before or after the conversion of compounds (IV)/(V) to compound (VI)) may not be done in any order.

Moreover, the enablement requirement does not require limiting the claims to preferred embodiments. *See* MPEP § 2164.08 (citing *In re Goffe*, 542 F.2d 564, 567 (CCPA 1976) (“To demand that the first to disclose shall limit his claims to ... materials which meet the guidelines specified for ‘preferred’ materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts.”)).

For the foregoing reasons, claims 1, 10, 11, 13, 15-21, and 23-27 are enabled. The applicants respectfully request that the rejection be withdrawn.

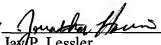
Claims 2-9, 12, 14, 22, and 28-40 have been rejected only as depending from a rejected base claim. The rejection to their base claims has been addressed and is believed to be overcome. Thus, withdrawal of this rejection is respectfully requested.

**CONCLUSION**

In view of the above amendments and remarks, the applicants believe the application is in condition for allowance. If there are any remaining issues that the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is kindly requested to contact the undersigned at the telephone number indicated below.

Dated: August 22, 2008

Respectfully submitted,

By  Reg. No. 60,473  
Jonathan P. Lessler  
Registration No.: 41,151  
DARBY & DARBY P.C.  
P.O. Box 5257  
New York, New York 10150-5257  
(212) 527-7700  
(212) 527-7701 (Fax)  
Attorneys/Agents For Applicant